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Pesticide Fact Sheet Number 27: Heliothis NPV

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16. Abstract (Limit: 200 words)

This document contains up-to-date chemical information, including a summary of the Agency's regulatory position and rationale, on a specific pesticide or group of pesticides. A Fact Sheet is issued after one of the following actions has occurred.

1. Issuance or reissuance of a registration standard,
2. Issuance of each special review document,
3. Registration of a significantly changed use pattern,
4. Registration of a new chemical, or
5. An immediate need for information to resolve controversial issues relating to a specific chemical or use pattern.

17. Document Analysis a. Descriptors

Pesticides, regulations, Chemical Information Fact Sheet, Use Patterns, Science Findings

b. Identifiers/Open-Ended Terms

c. COSATI Field/Group

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Office of Pesticides and Toxic Substances
Office of Pesticide Programs (TS-788C)
Washington, DC 20460

EPA

Pesticide Fact Sheet

Name of Chemical: Heliothis NPV
Reason for Issuance:
Date Issued: June 30, 1984
Fact Sheet Number: 27

1. Description of Chemical

Generic Name: Heliothis zea (NPV)

Common Name: Heliothis

Trade Names: Elcar, Biotrol VHZ and Viron/H

EPA Shaughnessy Code: 107301

Chemical Abstract Service (CAS) Number: 456H

Year of Initial Registration: 1975

Pesticide Type: Viral Insecticide

2. Use Patterns and Formations

Elcar® (Heliothis zea NPV) is registered for use on a variety of crops. There is also an exemption from the requirements of a tolerance established for the residues of this microbial insecticide nuclear polyhedrosis virus of Heliothis zea, in or on all raw agricultural commodities including:

Application Sites and Rates:

Terrestrial Food Use	Rates (lbs. active ingredient)
Beans Corn Lettuce Peanuts Sorghur Soybeans Strawberry Tomato Cotton	Application rates may vary from 0.001 to 0.25 pounds per acre
Terrestrial Non Food	
Tobacco	

3. Science Findings

Summary Science Statements:

Heliothis zea NPV does not appear to be toxic to man or animal; it does not appear to have any deleterious effects on the environment. Heliothis zea NPV has not been shown to be neurotoxic, oncogenic, teratogenic or mutagenic in the studies that have been reviewed to date.

Additional data are needed to determine the toxicity of Heliothis zea NPV to wildlife. From the available data, limited exposure to large animals, estuarine/marine organisms and freshwater organisms is expected as a result of the current label uses.

Chemical/Microbial Characteristics:

The nuclear polyhedrosis virus (NPV) of cotton bollworm Heliothis zea is a member of the occluded virus group of baculoviruses which have unusually complex structure. It contains double-stranded deoxyribonucleic acid genome enclosed within a nucleocapsid in the polyhedral inclusion body. The viral DNA is heterogenous in size with contour lengths ranging from 15 to 45 millimicrons, and has an estimated molecular weight of 30 x 10^6 daltons.

They are rods or cylinders and ellipsoids or oval structures. The size of the enveloped virions ranges from 60 to 70 millimicrons in width by 260 to 300 millimicrons in length. The polyhedral inclusion bodies of Heliothis zea NPV which also vary in both shape and size, ranging from 0.65 to 1.93 microns in diameter, can be observed easily under the light microscope.

The polyhedra which are made of large crystals of protein, are insoluble in water, withstand freezing and a wide range of environmental temperatures, and are resistant to bacterial putrefaction and to chemical treatments. However, the polyhedral inclusion bodies of Heliothis zea can be readily inactivated by short exposure to natural and artificial sunlight, and are susceptible to the treatment at high pH with solutions such as 0.1 M sodium carbonate. The treatment of polyhedra at high pH can be used to free the virions.

Toxicology Characteristics:

The means by which the Heliothis NPV infect the insect hosts are not fully understood at present. Virus may be aquired either by mouth, transovarially, or as a result of injury, for example, through parasitism; oral infection is the most common by far of these three modes of acquisition. It is reasonable to believe that the high pH (pH 9.5 to 10) of the anterior midgut with some enzymic virus degradation activity is adequate to initiate polyhedral dissolution and virion release. Once released, virions are directly exposed to the chemical conditions within the midgut lumen and enter into midgut cells. Virion occlusion begins by the disposition of polyhedral material around single virion and later the polyhedron enlarges to incorporate additional virions. It is uncertain how the polyhedral enlargement occurs. However, when a large dose of Heliothis NPV was fed to animals, the infective Heliothis NPV was only detected in the alimentary tract, but greater than 99.9% of the total virus infectivity was either destroyed or excreted within 48 hours. All animals remained healthy and no adverse effects of the treatment were reported. Similarly, infective Heliothis NPV was completedly destroyed after two hours incubation in human gastric juice.

Ecological Characteristics:

There are no data on the acute oral toxicity of Heliothis zea to birds. This data requirement remains unfulfilled. No data were received relating to the acute pathogenicity of Heliothis NPV to birds. This guideline requirement remains unfilled. No data were received relating to toxicity/pathogencity of Heliothis to freshwate. invertebrates, thus this guideline requirement remains unfulfilled.

Six studies on a formulated product of Heliothis were found to be acceptable for use in a hazard assessment. They are: LC_{50} values for rainbow trout at 10% virus were reported at approximately 96 hours, as being 2.06 ppm; white sucker at 10% test product, no effect at 100 ppm after 96 hours; black bullhead at 10% virus product showed no effect at 10 ppm; rainbow trout at 10% virus product resulted in 100% mortality in test solutions containing greater than 10 ppm concentrations after 96 hours; white sucker and black bullhead showed no effect at 70 ppm after 96 hours.

To address the ecological hazards, the Agency is requiring that the test results from all of the Tier I non-target organism tests, as noted in the current guidelines,

be submitted in support of registration or reregistration of all products containing the active ingredient Heliothis zea.

Tolerance Exemption Assessments as per 40 CFR §180.1027:

Exemptions from the requirement of a tolerance are established for the residues of the microbial insecticide nuclear polyhedrosis virus of Heliothis zea, in or on all raw agricultural commodities including: corn, cottonseed, beans, lettuce, okra, peppers, sorghum, soybeans, tobacco, and tomatoes.

4. Summary of Regulatory Position and Rationale:

Because all Heliothis zea products were registered under the conventional pesticides data requirement guideline before the promulgation of the current biorational guidelines, the Agency is requiring that all product analysis data be submitted as in Tier I of the biorational data guidelines, as well as most of Tier I data for Ecological Effects.

5. Summary of Major Data Gaps

The data requirements represent major data gaps for Heliothis NPV. These data are required to be submitted to the Agency within 2 years from the date of the issuance of the registration document.

Tier I §158.165 Nontarget Organisms

- Primary dermal study - Avian oral toxicity study
- Wild mammal study
- Freshwater fish study
- Freshwater aquatic invertebrate study
- Estuarine/marine animal testing study
- Plant studies
- Non-target insect study
- Honeybee testing study
- Product analysis data

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